

## **REMARKS**

The Applicants acknowledge the Examiner's comprehensive Office Action, a **Final Rejection**, with appreciation. Claims 1, 4, 5, 10, and 13 remain pending in the application. The previous rejections under 35 USC § 112, first and second paragraphs, as well as the previous prior art rejection under 35 USC § 102 have been withdrawn; however, the Office raises a new rejection under 35 USC § 102.

The Office makes the instant rejection Final because the previous Amendment is alleged to have necessitated new ground of rejection. The Applicants traverse this erroneous and prejudicial holding on the grounds that the noted amendment was nothing more than an amendment which limited the scope of the invention to subject matter already claimed and specifically noted by the Office to be under examination. For the Office to allege that the amendment necessitated the new ground of rejection is alternatively an abuse of discretion on the part of the Office or an acknowledgement by the Office that the full scope of the claims previously under examination was not, in fact, examined. In either event, the Office has erred and the instant imposition of a Final Rejection is improper. The Applicants, consequently, petition for withdrawal of the instant improperly and prejudicially imposed Final Rejection.

The claims are rejected under 35 USC § 102(b) as being anticipated by the previously cited Shapiro reference (US Patent No. 5,668,117). It is the position of the Office that Shapiro discloses treating neurological diseases, such as Pick's disease, with a composition comprising memantine, and that, although the cited reference does not disclose the instantly claimed mechanism of action, the reference discloses the same active agent for the treatment of the same conditions.

The Applicants respectfully submit that Shapiro discloses that NMDA receptor antagonists, including memantine, may be used to treat neurological diseases, such as Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, olivoponto cerebellar atrophy, and Alzheimer's disease. The Shapiro disclosure attributes the therapeutic action of memantine to its activity at the NMDA receptor.

Moreover, the Applicants respectfully submit that the Shapiro reference does not actually disclose treatment of Pick's disease with memantine. The Shapiro reference discloses that therapeutic compositions comprising at least one carbonyl trapping agent may be used to treat neurological diseases which involve chemical crosslinking of neurofilaments (including Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, olivoponto cerebellar atrophy, and Alzheimer's disease). The reference further discloses that there is evidence to suggest that such chemical crosslinking of neurofilaments is involved in the etiology of Pick's disease.

The Shapiro reference also discloses that the disclosed carbonyl trapping agents may be used in combination with pharmaceutical agents *previously recognized* as having some medicinal value for the treatment of specific neurological diseases and that NMDA receptor antagonists, including memantine, have been previously reported to be useful in treating neurological diseases, such as Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, olivoponto cerebellar atrophy, and Alzheimer's disease. There is, however, no disclosure in the Shapiro reference related to the treatment of Pick's disease with NMDA receptor antagonists.

Example 1 of the Shapiro reference is cited by the Office as disclosing compositions comprising memantine for the treatment of neurological diseases such as Pick's disease; however, Example 1 discloses the use of a carbonyl trapping agent in combination with a known medicament (including an NMDA receptor antagonist, such as memantine) for the treatment of Parkinson's disease. Moreover, the remaining Examples disclosed in the Shapiro reference only include NMDA receptor antagonists (such as memantine) in combinations which are disclosed to treat conditions which are known to be treatable by NMDA receptor antagonists.

Thus, the Applicants respectfully submit that there is no disclosure in the Shapiro reference to teach or suggest treatment of Pick's disease with compositions comprising memantine, and the Applicants respectfully reiterate that the instant claims, as currently amended, do not encompass treatment of the conditions disclosed in the Shapiro reference. Moreover, treatment of instantly claimed conditions may be correlated with the ability of the instant compounds to inhibit abnormal hyperphosphorylation of microtubule protein *tau*. One skilled in the art

would not have predicted such activity based on the disclosure of memantine as an NMDA receptor antagonist. Thus, the Applicants respectfully reiterate that the instantly claimed method is not anticipated nor rendered obvious by the disclosure of the cited reference.

Reconsideration and withdrawal of the anticipation rejection under 35 USC § 102(b) is respectfully requested.

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Accordingly, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

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**THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.**